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8EHQ-0296-05765

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U.S. Environmental Protection Agency  
401 "M" Street, S.W.  
Washington, D.C. 20460

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EPA Document Control No.:  
8EHQ-1185-0576

Dear Sir/Madam:

In May, 1987 submitted a TSCA Section 8(e) notification on the toxicity of Clarified Slurry Oil (CAS 64741-62-4) and the relationship between subchronic and developmental toxicity and chemical composition. Supplemental submissions to this 8(e) have been made as testing on this and several other refinery streams progressed. The report accompanying this letter does not meet our interpretation of criteria for TSCA Section 8(e) reportability because of the high doses used in the study and the specific effects observed. However, it is being submitted because it complements previous studies on Clarified Slurry Oil and other PNA containing streams.

In the enclosed study, rabbits were dosed once dermally with 1 to 3 ml/animal (approximately 450 to 1350 mg/kg) Clarified Slurry Oil or Syn-tower Bottoms. At 3 and 14 days after dosing, treated animals showed decreased body weight gain and thymus weight, and visible changes in the appearance of the liver. Microscopic changes were found in both liver and thymus. All but one treated animal survived.

Moderate skin irritation was also observed for Clarified Slurry Oil. Primary Irritation Index (PII) scores calculated on the third day of the study in accordance with recommended test procedures were somewhat lower than scores calculated at 7, 10 and 14 days after dosing. Therefore, the usual recommended observation time underestimates the irritancy of these materials. We believe the effects seen in this study, except for skin irritation, are due largely to polycyclic aromatic compounds, in agreement with conclusions reported in our previous submissions.

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Study #	CAS #	Test Article
61806	64741-62-4	Clarified Slurry Oil (CSO)/Syn-tower Bottoms (STB)

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Confidentiality is being claimed for company identifiers and names of company employees. All pages containing this information have been stamped "Confidential". Two copies of this notification are being submitted; the confidential information has been circled in one copy and excised from the other. The latter copy is intended for the EPA's public files. The substantiation for this claim is attached.

If you have any questions concerning the attached documents, I can be reached at 609-737-5945.

Yours truly,

Enclosures

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## SUBSTANTIATION OF CONFIDENTIALITY CLAIM

Confidentiality is being claimed for the submitter's identity and the names of company scientists which appear in the submission.

1. This confidentiality claim is being made on behalf of
2. No time limit is specified for this claim since we cannot assign a time at which the materials being reported will no longer be of commercial interest to the submitter.
3. The report contained in this submission has not been previously submitted to any governmental agency.
4. The report is kept in an Archive and other company confidential files to which access is restricted to authorized personnel.
5. No one outside has access to the report involved in this confidentiality claim.
6. The information for which confidentiality is being claimed does not appear in any advertising or promotional material, material safety data sheet, technical data sheet, professional or trade publication, or any other media available to the public or to our competitors.
7. To our knowledge, no confidentiality determinations have been made by the EPA, other Federal agency, or court in connection with this information.
8. These claims are being made in order to retain maximum utility of the information for the corporation which incurred the costs of the study being reported.
9. The refinery stream discussed in this submission is not patented.
10. The substance covered by this submission has been commercially available and/or manufactured by our competitors for many years.
  - a. Our competitors are aware that this stream or products made from it are on the market.
  - c. This material is used primarily as a feed for other refinery processes.
11. Reverse engineering is not an issue in this confidentiality claim.
12. Disclosure of this information would not reveal confidential processes or concentrations of substances in a mixture. The information claimed as confidential is unrelated to the effects of the substances on human health or the environment.
13. A CAS number is provided in the submission cover letter.
14. The subject of this notification and the information being claimed confidential are not subject to FIFRA regulation or reporting.

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**Composite skin irritation from a single application of clarified slurry oil (CSO) and dermal toxicity from a single application of CSO or Syn tower bottoms (STB)**

**Study Number: 61806**

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REPORT RELEASE

TO STUDY DIRECTOR/LIAISON:

STUDY NUMBER: 61806

CRU NUMBERS: 86001, 86484

SAMPLE NAMES: Clarified Slurry Oil, Syn Tower Bottoms

STUDY TITLE: Composite skin irritation from a single application of clarified slurry oil (CSO) and dermal toxicity from a single application of CSO or Syn tower bottoms (STB)

REQUESTING DIVISION:

RESULTS:

Skin irritation from CSO was slight during the first 3 days after dosing, but increased over 10 days to more severe levels. Thus the standard PII scores are misleadingly low. These results parallel those in an earlier study (61705) with STB. Four of 6 animals dosed with CSO in the composite component of the present study lost weight over the 14 days after dosing.

Dosing animals with 1 ml/animal of CSO or STB produced significant liver toxicity similar to that seen in study 61705 with STB. Macroscopic and microscopic liver lesions were present on day 3 and day 14. Macroscopic lesion incidence was increased on test day 14 relative to day 3; microscopic liver lesions appeared to be progressive without evidence of resolution on test day 14. No marked alterations in serum chemistry parameters were noted on day 3 or 14 after dosing with CSO or STB. Organ weight data indicated a marked reduction in the thymus weights of both male and female animals exposed to CSO or STB. Microscopic examination revealed thymic lesions. Thymus weights and the incidence and severity of microscopic findings appeared to be more affected on day 3 than day 14. However, this may be an artifact of the small group size.

\_\_\_\_\_  
8-1-95  
Date  
Study Director

\_\_\_\_\_  
8/21/95  
Date  
Vice President

\_\_\_\_\_  
8/21/95  
Date  
President

DISTRIBUTION: Liaison, Database, Study Director (Original and 2 copies)

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**REPORT ON COMPOSITE SKIN IRRITATION FROM A SINGLE APPLICATION OF  
CLARIFIED SLURRY OIL (CSO) AND DERMAL TOXICITY FROM A SINGLE  
APPLICATION OF CSO OR SYN TOWER BOTTOMS (STB)**

Study No.: 61806

Liaison:

Requesting Division:

**INTRODUCTION AND SUMMARY**

This study resulted from observations in a previous acute skin irritation study (#61705) with Syn Tower Bottoms in which liver toxicity was observed 2 weeks after a single dermal exposure. This previous study involved the application of a total of 1g/kg to the skin under both occlusive and nonocclusive conditions on each rabbit.

Syn Tower Bottoms (STB) and Clarified Slurry Oil (CSO) should be similar in composition and presumably have similar toxicity. However, sufficient data was not available on the course of effects after an acute exposure with each material and therefore the present study was conducted. The study had 4 main objectives:

- 1) to determine if CSO, in a skin composite study, will give the same irritation and effects on the liver as were produced by STB in study #61705,
- 2) to determine if STB dosed at 1 ml/animal under occlusive conditions for 24 hours would produce lesions in the liver and other signs of toxicity by day 14 similar to those in study #61705 (a composite skin irritation assay),
- 3) to determine if CSO produces similar liver toxicity when applied for 24 hours under occlusion at a dose of 1 ml/animal as it did in a composite test,
- 4) to determine whether observable toxicity occurs quickly (by the third day) after a 24-hour application of CSO or STB at 1 ml/animal.

Regarding the first-objective, skin irritation from CSO was slight during the first 3 days after dosing, but increased over 10 days to more severe levels. Thus the standard PII scores are misleadingly low. These results parallel those with Syn Tower Bottoms. Four of 6 animals dosed with CSO in the composite component of this study (group 1) lost weight over the 14 days after dosing.

For objectives 2, 3, and 4, dosing animals with 1 ml/animal produced significant liver toxicity similar to that seen in study 61705 with STB. The livers of animals dosed with 1 ml/animal of CSO or STB (groups 2 and 3) had macroscopic and microscopic lesions on day 3 and day 14. The macroscopic findings included areas of black, yellow, and/or white discoloration with some of the yellow discolored areas

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being abnormally firm. The incidence of discoloration of the liver was increased on day 14 relative to day 3 (4 versus 1 animals). Microscopic changes included cellular degeneration with a distinct color gradation of the cellular cytoplasm on test day 3. Microscopic liver changes on test day 14 included ballooning degenerative hepatocytes, with the central lobular and midzonal sections appearing the most effected, cytoplasmic rarefication, areas of fibrosis, reactive hyperplasia and hepatocyte hypertrophy and necrosis. These microscopic liver findings appeared to be progressive without evidence of resolution on test day 14.

Organ weight data indicated a marked reduction in the thymus weights of both male and female animals exposed to CSO or STB. Microscopic examination of the thymus of animals exposed to CSO or STB sacrificed on days 3 and 14 revealed an abnormally thin thymus cortex with increased macrophage numbers. Thymus weights and the incidence and severity of microscopic findings of animals sacrificed on day 3 appeared to be more affected than those sacrificed on day 14. However, this may be an artifact of the small group size.

There were no marked alterations in parameters of serum chemistry on day 3 or 14 after dosing with 1 ml/animal CSO or Syn Tower Bottoms. It is uncertain if macroscopic changes in other organs were a direct result of test material exposure, a by-product of significant liver toxicity, or incidental background occurrences.

#### EXPERIMENTAL DESIGN AND METHODS

This study employed all rabbits available at the time, but the number of animals in each group was limited nonetheless. Twenty-four White New Zealand rabbits were divided into the following 4 groups:

Group	No./ Sex	Material*	Type of Treatment	Necropsy Day
1	3M,3F	CSO	composite irritation model**	14
2	2M,2F	CSO	site occluded, 24 hours	3
	2M,2F	STB	site occluded, 24 hours	3
3	2M,1F	CSO	site occluded, 24 hours	14
	2M,1F	STB	site occluded, 24 hours	14
4	1M,3F	—	control animals	14

\* Group 1 animals received a 0.5 ml dose at each of 6 sites for a total dermal dose of 3.0 ml; groups 2 and 3 received 1 ml of test material on one test site. Controls (group 4) were not dosed with test material.

\*\* See Appendix A.

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Blood samples were collected for clinical chemistry and hematology from each animal in all groups prior to dosing. For groups 1, 3, and 4, blood was collected again on day 3 and day 14 after treatment; blood was taken from group 2 on day 3.

Skin irritation scores were determined on all treated groups (1-3) through day 3. In addition, treated sites in group 1 were evaluated for irritation through day 14. More specific information on dosing and scoring for irritation is in Appendix A.

Animals were weighed on the day prior to treatment and again prior to sacrifice. The animals were checked twice daily for mortality, at least 5 hours apart on workdays and at least once daily on weekends and holidays. The animals were also observed once daily during normal work days for any indications of toxicity. On the days of the scheduled sacrifices, all rabbits were weighed, anesthetized, sacrificed, and necropsied. The following tissues from each animal were preserved in 10% neutral buffered formalin:

liver*	spleen*	testes*	intestine
kidneys*	stomach	ovaries*	adrenals
thymus*	bone	uterus	heart
thyroid	pancreas	lung	prostate
thigh muscle	sciatic nerve	treated skin	

Those organs marked with an "\*" were weighed (paired organs weighed together). Additional information on the conduct of the study is in Appendix B.

#### **RESULTS: SKIN IRRITATION IN COMPOSITE STUDY WITH CSO (GROUP 1)**

The results of the skin irritation study with CSO in the composite skin irritation model are summarized here.

Index of Irritation	Minimum Score for Irritant Rating	Actual Score
DOT Corrosion	NA	Negative
EEC (4 hr occluded)		
Erythema	2.0	1.0
Edema	2.0	0.5
OSHA (4 hr occluded) PII	5.0	1.5
FHSA (24 hr occluded) PII	5.0	2.0
24 hr non-occluded PII	NA	1.9



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CSO was not corrosive to the intact skin of New Zealand White rabbits when applied under an occlusive dressing for 4 hours and evaluated as per the DOT procedure (Code of Federal Regulations, Title 19, Part 173, Section 173.1300).

Mean values for erythema and edema were calculated as suggested by EEC guidelines for labeling, i.e., from the scores obtained at the intact sites at 24, 48, and 72 hours. CSO was not a skin irritant under the EEC guidelines.

The Primary Irritation Index (PII) was calculated from the first and third days after a 4-hour exposure on intact skin sites, in accord with OSHA guidelines (Appendix A to Section 1910.1200 of the CFR). CSO was not a skin irritant under the OSHA system of classification.

The FHSA and PII's represent the means for irritation scores after a 24-hour exposure on occluded and nonoccluded sites, respectively. Both intact and abraded sites were scored on day 1 and 3 after exposure. CSO was not a skin irritant by the FHSA classification. CSO bordered between a slight and moderate irritant under the Toxicity Guidelines in force at the time the study was conducted. Neither occlusion, abrasion, or duration of exposure appeared to significantly affect irritation.

The relatively mild irritation scores under EEC, OSHA, and FHSA are based on observations only up to 3 days after application. Irritation increased after the third day, as indicated in the following summary table. Thus these standard scores do not provide an accurate indication of the irritancy of CSO.

Mean Erythema (ER) and Edema (ED) Scores by Site

Day	4-Hour Occluded		24-Hour Occluded		24-Hour Nonoccluded	
	ER	ED	ER	ED	ER	ED
1	1.0	0.4	1.7	1.0	*	1.0
2	1.0	0.4				
7	2.2	1.9	2.3	2.0	2.3	2.5
10	2.8	1.9	3.3	2.5	3.4	2.7
14	2.7	1.5	3.2	2.3	3.3	2.8

\* Staining of the skin with CSO prevented scoring.

Irritation scores were greater with 24-hour treatment than with 4-hour dosing at day 1 and days 10 and 14. Curiously, there was no difference at days 3 and 7. Neither occlusion or abrasion appeared to significantly affect irritation.

**CONFIDENTIAL****RESULTS****CLINICAL OBSERVATIONS IN COMPOSITE STUDY WITH CSO (GROUP 1)**

In terms of clinical appearance, all animals in group 1 were normal until day 8 after dosing. At that time, the following signs were observed:

Day of Study	Reduced urine and feces	Reduced food consumption	Mucus in stool	Thin appearance	Loose stool
8	1M,1F	1M,1F			
9	1M,1F	1M,2F			
10	1M,2F	1M,2F	1M,1F		
13	1M,1F	1M,1F		3M,3F	
14	1M,1F	1M,1F	1M		1M,2F

Reductions in food consumption and in urine and feces were evaluated subjectively and were not measured quantitatively. The subjective observation of "thin appearance" was substantiated by weight loss measured in most of the animals during the 2 weeks of the study, as can be seen in the following table.

**Individual body weights (kg) of rabbits in group 1.**

Animal No.	Sex	Weight before dosing	Weight on day 14
027-261	M	2.2	2.3
027-262	M	2.4	1.8
027-263	M	2.4	2.3
027-272	F	2.5	1.9
027-273	F	2.3	2.4
027-274	F	2.2	2.1

**RESULTS: COMPARISON OF CSO AND SYN TOWER BOTTOMS (GROUPS 2 - 4)**

Similar clinical observations were made among rabbits in group 3 treated with CSO or STB. Animals in group 3 appeared normal until day 8 after dosing. From day 8 to 14, decreased food consumption, decreased feces, decreased urine, loose stool, and thin appearance were observed among some of the rabbits treated with CSO or STB.

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No rabbits in group 3 actually lost body weight, but these treated animals gained slightly less than the controls animals over the 2 weeks of the study. (See following table.) No clinical abnormalities were noted in animals in groups 2 or 4, however, one female in group 2 was found dead approximately 24 hours post-dosing. The surviving animals in group 2 were sacrificed on day 3 and all animals in groups 3 and 4 were sacrificed on day 14.

Body weight (Kg) among rabbits of groups 3 and 4.

Group	Animal	Sex	Body Weight (kg) at		Mean Increase in Body Weight (Kg)
			Day 0	Day 14	
<hr/>					
Group 4:					
control	027-266	M	2.4	2.6	0.28
	027-277	F	2.2	2.6	
	027-278	F	2.3	2.5	
	027-279	F	2.7	3.0	
Group 3:					
CSO	027-259	M	2.7	2.9	0.13
	027-260	M	2.5	2.5	
	027-271	F	2.6	2.8	
STB	027-267	M	2.6	2.6	0.03
	027-268	M	2.5	2.6	
	027-280	F	2.6	2.6	
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## CLINICAL CHEMISTRY

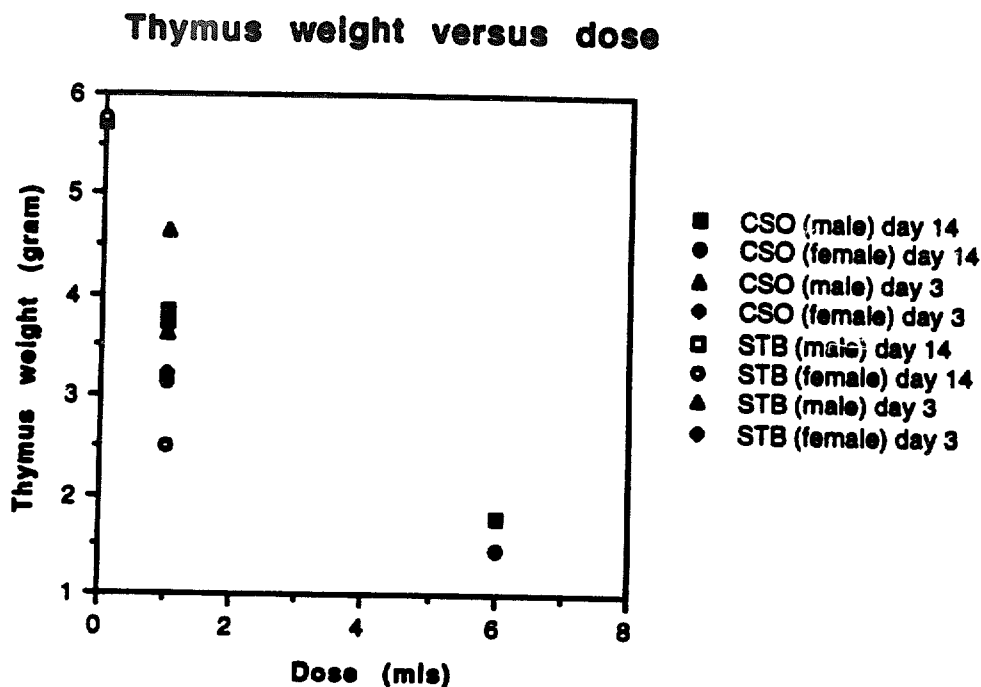
Data on clinical chemistry was marked by variability and no statistical analyses were performed because of the low numbers of samples. There were no obvious changes in the parameters as a result of treatment with CSO or STB in samples collected at 3 or 14 days after application.

## ORGAN WEIGHT DATA

Data on organ weight data was marked by variability and no statistical analyses were performed because of the low numbers of samples. There were no obvious changes in the parameters as a result of treatment with CSO or STB in kidney, liver, spleen, testes or ovary organ weights at 3 or 14 days after application. However, thymus weights of both male and female animals exposed to either CSO or STB sacrificed on

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day 3 or two weeks after dosing were depressed relative to controls as illustrated below.



### OBSERVATIONS AT NECROPSY

Animals in group 1 treated with CSO and STB were sacrificed on day 15. Each animal received a 0.5 ml dose at each of 6 sites for a total dermal dose of 3.0 ml. Of the 6 animals examined macroscopically at necropsy, 5 displayed macroscopic liver lesions; 4 animals displayed a marked reduction in thymus size; 2 animals displayed abnormalities in the glandular mucosa of the stomach; and one animal displayed both heart and spleen abnormalities. Group 1 tissues were not examined microscopically.

Animals in group 2 treated with CSO and STB (1 ml/animal) were sacrificed on day 3. Two animals treated with CSO and one animal treated with STB exhibited macroscopic findings. One CSO treated male exhibited two small areas of the glandular stomach mucosa thickened and lifted from the stomach surface. The CSO treated female found dead at ~ 24 hours exhibited a slightly smaller stomach, slightly reddened appearance of the lungs, and the large and small intestines filled with a green liquid. One animal exposed to STB exhibited macroscopic liver lesions.

Animals in group 3 treated with CSO and STB (1 ml/animal) were sacrificed on day 14. Two CSO treated animals exhibited macroscopic findings at necropsy. One male

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displayed a single macroscopic liver lesion of moderate size (3\*3.5 cm), and one female displayed numerous bilateral kidney cysts. All three animals treated with STB exhibited macroscopic liver lesions.

All animals in group 4 were judged to be normal.

#### **MICROSCOPIC OBSERVATIONS**

Tissues of group 1 animals were not examined microscopically.

Microscopic examination of animals treated with CSO or STB sacrificed on day 3 (group 2) revealed signs of significant liver toxicity as indicated by cellular degeneration with distinct color gradation of the cellular cytoplasm with dark cytoplasmic clumps of cellular constituents partially or wholly surrounding the nucleus with sharply contrasting pale vacuolated cytoplasm around the periphery of the cell. Also, most group 2 animals exhibited an abnormally thin thymus cortex with increased macrophage numbers. Microscopic examination of the glandular portion of the stomach judged to be abnormal during macroscopic examination was judged to be normal by the study pathologist. Unfortunately the other two macroscopic stomach lesions were in group 1 animals which were not examined microscopically. However, due to the high incidence, 2 of 6 animals treated with 3.0 mls CSO and 1 of 7 animals treated with 1.0 mls CSO, this finding can not be dismissed as incidental. It may be test material induced, a by-product of exposure to the test material or an incidental occurrence unrelated to test material exposure.

Microscopic examination of animals treated with CSO or STB sacrificed on day 14 (group 3) revealed a continuation of the liver toxicity without obvious signs of resolution. All animals displayed microscopic liver changes which included ballooning degenerative hepatocytes with the central lobular and midzonal sections appearing most effected. Cytoplasmic rarefaction, areas of fibrosis, reactive hyperplasia, and hepatocyte hypertrophy and necrosis. Microscopic changes of the thymus appear with less incidence and severity than at the day 3 sacrifice.

Tissues of control animals did not reveal any abnormal findings.

2-21-95  
Date

Study Director

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## Appendix A. Information on Dosing of Test Materials

### Administration of CSO to Group 1

The backs of the Group 1 animals shaved on the day prior to dosing. A total of six sites were arranged on each rabbit's back in the following manner: two anterior sites were occluded for 4 hours, two mid-dorsal sites were occluded for 24 hours, and two posterior sites were left uncovered. The right hand sites were abraded (approximately 2-3 cm square).

On day 0, each skin site was treated with 0.5 ml of CSO, measured and dosed with a 1 cc x 0.01 cc tuberculin syringe. For the occluded sites the compound was administered underneath a Webril patch (approximately 1" square), secured with a non-irritating surgical tape and then wrapped with an occlusive rubber dam and adhesive tape. The animals were fitted with Elizabethan-style plastic collars to limit access to the test sites and prevent licking of the test material. The test sites were unwrapped and examined under the following schedule:

**Day of Dosing (Day 0):** The 4-hour occluded sites were unwrapped and evaluated for corrosion. They were then wiped with saline. After 30 minutes, both sites were evaluated for skin irritation according to the scale of Draize.

**24 Hours after Dosing (Day 1):** The 24-hour occluded sites were unwrapped and wiped with saline. Nonoccluded sites were also wiped. After 2 hours (at 26 hours after dosing), both occluded and nonoccluded sites were scored for irritation. Collars were removed. After an additional 2 hours (approximately 24 hours after removal of the patches) the 4-hour occluded sites were scored for irritation.

**48 Hours after Dosing (Day 2):** The 4-hour occluded intact skin site was evaluated for corrosion.

**52 Hours after Dosing (Day 2):** The intact and abraded 4-hour occluded sites were scored for irritation (OECD).

**72 Hours after Dosing (Day 3):** The 24-hour occluded and non-occluded sites were scored for irritation. With scores of 2 or greater for the 24-hour occluded and non-occluded sites, the sites were evaluated again on days 7 and, if necessary, on days 10 and 14.

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**Appendix A Continued:**

**76 Hours after Dosing (Day 3):** The intact and abraded 4-hour occluded sites were scored for irritation (OECD). With scores of 2 or more, these sites were evaluated again on days 7 and, if necessary, on days 10 and 14.

**14 Days after Dosing:** All animals in group 1 were sacrificed and necropsied.

**Administration of CSO or STB to Group 2**

The backs of the 8 animals were shaved on the day before dosing. On the day of dosing, 4 animals (2M, 2F) were dosed with 1 g/kg of CSO; the remaining 4 animals (2M, 2F) were dosed with 1 g/kg of Syn Tower Bottoms. Test sites were occluded for 24 hours, unwrapped, wiped, and scored until 72 hours after dosing in the same manner as for Group 1, except that collars were not removed until time of sacrifice after the 72-hour scoring interval.

**Administration of CSO or STB to Group 3**

The backs of the 6 animals were shaved on the day before dosing. On the day of dosing, 3 animals (1M, 2F) were dosed with 1 g/kg of CSO; the remaining 3 animals (1M, 2F) were dosed with 1 g/kg of Syn Tower Bottoms. Test sites were occluded for 24 hours, unwrapped, wiped, and scored in the same manner as for animals in Group 1. Collars were removed at the 72-hour scoring interval. The animals were sacrificed and necropsied at 14 days after dosing.

**Control Animals in Group 4**

The backs of the untreated control animals were shaved on the day before treatment of groups 2, 3, and 4. Collars were placed on the rabbits on the day of treatment for the other groups and removed on day 3. Rabbits in this group were sacrificed and necropsied on day 14.

**Determination of Scores for Skin Irritation**

Corrosion on the intact skin of New Zealand White rabbits was evaluated when test material was applied under an occlusive dressing for a 4-hour exposure and scored according to the DOT procedure (Code of Federal Regulations, Title 49, Part 173, Section 173.1300).

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**Appendix A Continued:**

Mean values for erythema (redness) and edema (swelling) were calculated as suggested by EEC Guidelines for labeling, i.e., from the scores obtained at the intact sites 24, 48, and 72 hours after the end of the exposure period.

The Primary Irritation Index (PII) was calculated from the scores on the first and third days after a 4-hour exposure on intact skin sites, in accord with OSHA Guidelines (Appendix A to Section 1910.1200 of the CFR).

The FHSA and . PIIs represent the mean value for irritation after a 24-hour exposure on occluded and nonoccluded sites, respectively. Both intact and abraded sites were scored on the first and third days after application.



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**Appendix B: Additional information on conduct of the study**

**Clarified Slurry Oil**

**CRU Sample No.: 86001**

**Receipt Date: 1/19/87**

**Physical State: Brown liquid**

**Storage Conditions: Store in a ventilated hood in Room 422.**

**Expiration Date: 9/86**

**Syn Tower Bottoms**

**CRU Sample No.: 86484**

**Receipt Date: 1/19/87**

**Physical State: Brown liquid**

**Storage Conditions: Store in a ventilated hood in Room 422.**

**Expiration Date: 9/30/91**

**No preparation was required for either test article.**

**Date of Initiation: 1-20-87**

**Date of Completion: 2-3-87**

**Animals:**

**Species: white New Zealand rabbits**

**Number and Sex: 12/sex**

**Source: Hazelton Research Animals, Denver, PA**

**Identification: individual eartags and cage cards**

**Age: young adult**

**Initial Body Weight Range: 2-3 kg.**

**Acclimation: minimum of 5 days at                      before use**

**Randomization: Animals are randomly assigned to cages upon receipt and, therefore, randomly assigned to dose groups within this study.**

**Observations for Mortality: twice daily on normal workdays and once daily on weekends**

**Observations for Toxic Signs: at least once daily on normal workdays**

**Calculations and Statistical Analysis of Data: none**

**Storage of Data and Reports: Protocol, report and original data for this study are stored at the**

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**CONFIDENTIAL****Appendix C: Incidence of Macroscopic findings at necropsy**

Grp	ID/Sex	Macroscopic finding
<b>1:</b>		
CSO	027-261 M	discolored liver
	027-262 M	discolored liver, small thymus, reddened stomach mucosa
	027-263 M	discolored liver,
	027-272 F	eroded glandular mucosa of stomach, discolored liver
	027-273 F	normal
	027-274 F	discolored liver, small thymus
<b>2:</b>		
CSO	027-264 M	eroded mucosa of stomach
	027-265 M	normal
	027-275 F	small thymus
	027-276 F	normal
	STB	027-269 M
027-270 M		normal
027-281 F		discolored liver
027-282 F		normal
<b>3:</b>		
CSO	027-259 M	normal
	027-260 M	discolored liver
	027-271 F	renal cysts
STB	027-267 M	discolored liver
	027-268 M	discolored liver
	027-280 F	discolored liver
<b>4</b>		
	027-266 M	normal
	027-277 F	normal
	027-278 F	normal
	027-279 F	normal

**CONFIDENTIAL****Appendix C: Individual organ weight data (g)**

Grp	ID/Sex	kidney	liver	spleen	testes	thymus
1 CSO	027-261 M	17.11	117.62	2.086	1.478	2.790
	027-262 M	16.37	64.21	0.831	3.230	0.953
	027-263 M	16.62	102.44	0.980	2.937	1.600
2 CSO	027-264 M	15.53	88.77	0.735	1.378	2.704
	027-265 M	17.19	99.08	1.112	2.040	4.539
2 STB	027-269 M	19.03	102.21	1.103	2.275	4.176
	027-270 M	19.01	97.21	0.896	1.667	5.113
3 CSO	027-259 M	21.62	110.77	2.245	4.626	4.434
	027-260 M	20.47	117.71	1.299	2.532	3.045
3 STB	027-267 M	16.30	97.04	1.237	3.415	3.782
	027-268 M	21.39	136.86	0.992	3.460	3.873
4	027-266 M	17.85	100.64	0.931	2.684	5.698

Grp	ID/Sex	kidney	liver	ovary	spleen	thymus
1 CSO	027-272 F	15.46	76.76	0.295	0.736	0.635
	027-273 F	17.87	87.52	0.154	1.135	3.128
	027-274 F	15.449	115.51	0.200	0.677	0.618
2 CSO	027-275 F					
	027-276 F	21.02	99.11	0.238	1.239	3.206
2 STB	027-281 F	16.98	110.92	0.344	1.802	5.348
	027-282 F	16.94	86.72	0.174	1.128	2.273
3 CSO	027-271 F	19.17	159.76	0.256	1.193	3.145
3 STB	027-280 F	20.62	133.16	0.234	1.244	2.485
4	027-277 F	16.96	96.25	0.239	1.245	5.705
	027-278 F	17.50	81.82	0.187	1.566	4.775
	027-279 F	20.85	124.96	0.358	1.467	6.809

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